

**REMARKS**

Claims 1-28 and 30-49 are pending in this application. Claims 1-27 and 30-42 are withdrawn from consideration to a non-elected status. Claims 28 and 43-49 were variously rejected under 35 U.S.C. § 112, first paragraph and under 35 U.S.C. § 112, second paragraph.

By this amendment, claim 28 has been amended and new claim 50 has been added without prejudice or disclaimer of any previously claimed subject matter. Support for the amendments and new claim can be found, *inter alia*, throughout the specification, for example, at page 4, lines 14-17 and page 15, lines 20-22.

The amendments are made solely to promote prosecution without prejudice or disclaimer of any previously claimed subject matter. With respect to all amendments and cancelled claims, Applicants have not dedicated or abandoned any unclaimed subject matter and moreover have not acquiesced to any rejections and/or objections made by the Patent Office. Applicants expressly reserve the right to pursue prosecution of any presently excluded subject matter or claim embodiments in one or more future continuation and/or divisional application(s).

Applicants have carefully considered the points raised in the Office Action and believe that the Examiner's concerns have been addressed as described herein, thereby placing this case into condition for allowance.

**Finality of Office Action**

The Office Action mailed January 5, 2003 is indicated to be a Final Office Action. However, a request for continuing examination under 37 C.F.R. § 1.114 and accompanying fee was filed in this application on November 26, 2003. This filing was acknowledged by the Examiner on page 2 of the outstanding Office Action.

Accordingly, Applicants respectfully request that the finality of this action be withdrawn.

Rejection under 35 U.S.C. §112, second paragraph

Claims 28 and 43-49 were rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants respectfully traverse this rejection.

Although Applicants believe that the claims were sufficiently definite when considered in view of the specification and the understanding of those of skill in the art, Applicants have attempted to respond to the concerns of the Examiner in order to enhance clarity and to facilitate disposition of the present case.

Accordingly, claim 28 has been amended to use Markush language to clearly indicate that the claimed polynucleotide comprises both a sequence providing replicative function (section (a)) and a vitamin B<sub>12</sub> biosynthesis gene sequence (section (b)). Applicants have also amended claim 28 to reflect language suggested by the Examiner with regard to the vitamin B<sub>12</sub> biosynthesis pathway as well as addition language in order to particularly point out the claimed invention to one of skill in the art.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, second paragraph.

Rejections under 35 U.S.C. §112, first paragraph

*Written Description*

Claims 28 and 43-49 were rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants respectfully traverse this ground for rejection.

The Examiner states that the specification does not contain any disclosure of the function and structure of the claimed genus of sequences that are at least 70% homologous to a sequence as defined under now section (i) or (ii).

Although Applicants maintain the traverse of this rejection for reasons of record, the claims have herein been amended so that section (iii) recites “a sequence that is at least 95% homologous to a sequence as defined under (i) or (ii).”

Applicants respectfully submit that, at the time the application was filed, a skilled artisan would readily be able to identify and/or test a given sequence for the claimed features in section (iii). For example, a simple sequence comparison will determine whether the sequence has 95% homology to SEQ ID NO: 1 over at least 100 contiguous nucleotides. In addition, biochemical assays for autonomous replication of a polynucleotide in a cell are described and exemplified in the specification (for example, in Examples 6 and 9) and are also well-known in the art.

Applicants respectfully note that Example 14 of the Office’s Written Description guidelines indicates one of skill in the art would conclude applicant’s possession of the necessary common attributes possessed by the members of the genus when the members of the genus have at least 95% structural identity to the disclosed species and the specification presents an assay by which variants with the claimed activity can be identified. The claimed invention certainly meets this standard.

Applicants respectfully disagree with the Examiner’s assertion that Applicants have failed to disclose adequate written description of sequences capable of providing for expression of an endogenous gene within *Propionibacterium*. Office Action, page 6. Applicants respectfully submit that sequences of use for gene expression in *Propionibacterium* are described in the

specification and were well known in the art at the time the application was filed. For example, see page 12, lines 2-7 and the Examples of the specification, as well as Japanese No. 08-56673, published March 5, 1996, which describes promoter regions capable of providing for expression of *Propionibacterium* genes.

The specification provides a description of sufficient, relevant, identifying characteristics of the claimed polynucleotides that one skilled in the art would recognize that the inventor had possession of the claimed invention when the application was filed. Applicants respectfully submit that the specification in combination with that known in the art adequately describes possession of the claimed genus to one skilled in the art. Thus, the pending claims are fully described in the specification as filed and Applicants respectfully submit that the written description requirement has been met.

#### *Enablement*

Claims 28 and 43-49 were rejected under 35 U.S.C. §112, first paragraph, because the specification allegedly does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The Examiner asserts that the specification does not enable any sequence that is at least 70% homologous to SEQ ID NO:1 or the claimed sequences. As noted above, claim 28 has been amended to recite a sequence that is at least 95% homologous.

Applicants respectfully submit that the specification demonstrates that nucleotides 1 to 1800 of SEQ ID NO: 1 are sufficient for maintain replicative function in *Propionibacterium*. Also as described above, the specification provides methods for testing replicative function of the

claimed variant sequences of SEQ ID NO: 1. Once provided with the sequence of SEQ ID NO: 1, its function, and the specification, Applicants respectfully submit that making a variant that is at least 95% homologous to the sequence as claimed and testing for replicative function is a routine matter practiced by the person of skill in the art.

Applicants note that the test for enablement is not whether a certain amount of experimentation is required to practice an invention, but rather whether the amount of experimentation is “undue.” *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). Applicants respectfully submit that the specification has provided a reasonable amount of guidance to the skilled artisan with respect to the direction in which the experimentation should proceed and that the skilled artisan would be able to extend the teachings of the specification and the art to the polynucleotide sequences as claimed. Applicants respectfully submit that the specification provides adequate guidance pertaining how to make and/or use the claimed process. Accordingly, the pending claims are in compliance with the enablement requirements.

In sum, Applicants submit that the pending claims fall within the subject matter that is described and enabled by the specification as filed. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, first paragraph.

**CONCLUSION**

Applicants believe that all issues raised in the Office Action have been properly addressed in this response. Accordingly, reconsideration and allowance of the pending claims is respectfully requested. If the Examiner feels that a telephone interview would serve to facilitate resolution of any outstanding issues, the Examiner is encouraged to contact Applicants' representative at the telephone number below.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorize the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. **251502009000**.

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